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(54) Inflatable percutaneous oxygenator with transverse hollow fibers

(57) An elongated intravenous percutaneous oxygenator is described having a first and a second set of hollow gas permeable and liquid impermeable fibers, the fibers of each set having an input end and an output end, at least three longitudinally spaced manifolds in communication with one of said input ends or output ends of said fibers, gas delivery means in communication with the input ends of said fibers and gas exhaust means in communication with said output ends and inflatable balloon means disposed longitudinally of said oxygenator so as to be surrounded by said fibers, and gas inflation means in communication with said balloon means for inflating and deflating the balloon means.

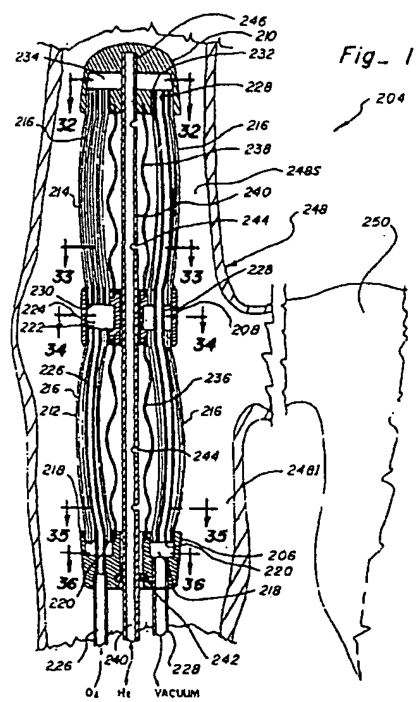

Fig_ 1

204

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Description

The present invention relates generally to gas transfer devices and more particularly to a percutaneous intravenous oxygenator utilizing hollow gas permeable fibers.

Many types of blood oxygenators are well-known in the art. For example, during open heart surgery, the patient is interconnected with an external oxygenator, commonly known as a heart-lung machine, which introduces oxygen into the blood system. Most types of oxygenators use a gas permeable liquid impermeable membrane. Blood flows along one side of the membrane, and oxygen is supplied to the other side of the membrane. Given a sufficient pressure gradient between the oxygen supply and the blood, the oxygen will diffuse through the membrane and into the blood. In addition, carbon dioxide will tend to diffuse from the blood through the membrane. In other situations, a smaller, implantable oxygenator may be sufficient to adequately supplement the patient's cardiopulmonary function by marginally increasing the oxygen content of the patient's blood. For example, patients suffering from emphysema, pneumonia, congested heart failure, or other chronic lung disease often have blood oxygen partial pressures of approximately 5320Pa(40 torr). A relatively small increase of 10% to 20% is generally sufficient to adequately maintain the patient. This is a particularly desirable alternative in that it avoids the need to intubate the patient in such cases. In addition, temporary use of this type of oxygenator is sufficient in many cases to tie the patient over in acute respiratory insult. Placing such patients on a conventional respirator is often the beginning of a progressive down hill spiral by damaging the patient's pulmonary tree and thereby causing greater dependence on the respirator.

The effective rate of diffusion in percutaneous oxygenators can be limited in some instances by the problem of "streaming" or "channeling," in which the blood stream establishes relatively stable patterns of flow around and through the oxygenator. Portions of the oxygenator are exposed to a relatively high velocity, turbulent flow of blood. These conditions tend to increase cross-diffusion of oxygen and carbon dioxide. However, other portions of the oxygenator are exposed to a low velocity, laminar flow of blood which reduces diffusion of gases Those portions of the oxygenator immediately adjacent to the regions of the high blood flow may continue to experience high rates of diffusion, but the remaining portions of the oxygenator tend to have relatively low diffusion rates. Thus, the overall diffusion rate of the oxygenator can be substantially diminished by streaming. A number of devices and processes have been invented in the past relating to different types of oxygenators.

US-A- 3,505,686 to Bodell demonstrates the general concept of using gas permeable fibers to boost the oxygen level of blood. The patent discloses several variations of the device wherein it is intended for use inside the body of the patient. In the implantable embodiment of the Bodell device, a tubular casing serves as a shunt either from the pulmonary artery to the left atrium of the heart or more generally between an artery and a vein. A multitude of parallel-connected capillary tubes are used to oxygenate and/or purify the blood circulating to the casing.

US-A- 4,583,969 to Mortenson shows a transvenous oxygenator made of a plurality of small diameter gas permeable tubes connected to headers at each end. However, the specific device disclosed by Mortenson has a significant disadvantage in that two incisions are required.

US-A-4,631,053 to Taherti discloses a transvenous oxygenator having a single membrane through which oxygen diffuses. The membrane is disposed within a sheath and both are supported by a flexible wire.

US-A- 4,850,958 to Berry, et al. discloses an in vivo extrapulmonary blood gas exchange device having a bundle of elongated gas permeable tubes bound at each end and enclosed within respective air tight proximal and distal chambers. A dual lumen tube is situated relative to the gas permeable tubes such that an outer lumen terminates within the proximal chamber and inner lumen terminates within the distal chamber.

US-A- 4,911,689 to Hattler and US-A-4,986,809 to Hattler, et al. disclose several embodiments of percutaneous oxygenators. In the simplest embodiment, oxygen is circulated through a plurality of hollow, gas permeable fibers forming loops and the device is inserted through a single incision into a blood vessel. In other embodiments, the fiber loops are bisected and placed in fluid communication within a mixing chamber within a tip at the distal end of the device.

Due to the inherent desirability and need for devices of the above-described type, continuing efforts are being made to improve the efficiency of the gas transferred provided by the device and it is to meet these needs that the present invention has been developed.

SUMMARY OF THE INVENTION

The present invention was developed to improve upon prior art oxygenators of the type that include hollow gas permeable/liquid impermeable membrane fibers that can be inserted into the vena cava to oxygenate blood intravenously. It has been found that the efficiency of such an oxygenators can be improved by minimizing the length of the fibers and/or deploying the fibers so that they do not run longitudinally of the device as in prior art systems. The blood gas transfer is also improved by maintaining constant movement of the gas fibers through use of an inflatable balloon around which the fibers extend.

Several embodiments of an oxygenator in accordance with the above teachings are disclosed.

In a preferred embodiment of the invention, at least

three longitudinally spaced manifolds are provided with one of the manifolds being in communication with for example the input ends of two sets of fibers and the other two manifolds being in communication with the output end of both sets of fibers so that gas is transferred in opposite directions from an intermediate location on the device through both sets of fibers. The fibers surround inflatable balloons disposed between the manifolds at each end of the oxygenator and the middle manifold. A desirable feature of this embodiment is that the fibers are of relatively short length which has also been found to improve the gas delivery efficiency of the fiber membrane oxygenators.

Other aspects, features and details of the present invention can be more completely understood by reference to the following detailed description of the preferred embodiments, taken in conjunction with the drawings, and from the appended claims.

Fig. 1 is a longitudinal section taken through a preferred embodiment of the present invention positioned within the vena cava and illustrating the heart adjacent thereto

Fig. 2 is an enlarged section taken along line 32-32 of Fig. 1.

Fig. 3 is an enlarged section taken along line 33-33 of Fig. 1.

Fig. 4 is an enlarged section taken along line 34-34 of Fig. 1.

Fig. 5 is an enlarged section taken along line 35-35 of Fig. 1.

Fig. 6 is an enlarged section taken along line 36-36 of Fig 1

Membrane type oxygenators are characterized in general by the fact that oxygen rich gas will diffuse through the membrane into oxygen deficient blood on the opposite side of the membrane while excess carbon dioxide in the blood will cross-diffuse through the same membrane into the oxygen stream. Accordingly, when a membrane oxygenator is inserted in a blood vessel and oxygen passed therethrough, the oxygen will diffuse through the wall of the fiber membrane thereby oxygenating the blood and simultaneously removing excess carbon dioxide from the blood

It should be appreciated that the oxygenator of the present invention could be used in other gas transfer environments such as for example to deliver an anesthetic A better description of this particular alternate use can be found in US-A- 5,207,640, which is hereby incorporated by reference.

A preferred embodiment 204 of the present invention is shown in Figs. 1- 6 and can be seen to include three longitudinally displaced manifolds 206, 208 and 210 which interconnect two distinct sets 212 and 214 of fibers 216. The manifolds 206 and 210 at the opposite ends of the oxygenator serve a common purpose in serving as inlet or outlet manifolds while the middle manifold 208 serves the opposite purpose. For purposes of the present disclosure, the middle manifold will be referred to as the inlet manifold and the other manifolds 206 and 210 will be referred to as the proximal end outlet manifold and the distal end outlet manifold, respectively. The proximal end outlet manifold 206 of the oxygenator is ring shaped and defines an internal chamber 218 that is in communication with the outlet end 220 of the first set 212 of fibers which have been potted in the manifold The inlet end 222 of the first set of fibers are potted in the inlet manifold 208 which also has a circular hollow chamber 224. An oxygen gas inlet line 226 is connected to (in non-fluid communication) and passes through the proximal end outlet manifold 206 and is connected to and communicates with the interior chamber 224 of the inlet manifold 208 for delivering gas to the inlet manifold. The gas is thereby allowed to flow in a reverse direction through the first set of fibers for collection in the proximal end outlet manifold 206 where the gas can be removed by a vacuum source connected through a vacuum line 228 to the hollow chamber 218 in the proximal end outlet manifold 206.

The second set of fibers 214 have their inlet end 230 potted in the inlet manifold 208 again in communication with the interior chamber 224 to receive oxygen gas therefrom and an outlet end 232 potted in the distal end outlet manifold 210 having a hollow chamber 234 in communication with the outlet end of the fibers. The vacuum line 228 extends through the proximal end outlet manifold 206, through the inlet manifold 208 (in non-fluid communication), and then opens into the internal chamber 234 in the distal end outlet manifold 210. In this manner, gas collected in the distal end outlet manifold can be returned to the proximal end outlet manifold 206 and subsequently removed from the oxygenator through the influence of the vacuum source.

It will therefore be seen that the inlet manifold 208 which is in communication with a source of oxygen gas is positioned to deliver gas to both the first and second sets 212 and 214 of fibers so that the gas flows in opposite directions from the inlet manifold and can be collected in both the distal and proximal end outlet manifolds for removal through the vacuum line 228. The vacuum source is therefore utilized to draw the oxygen gas through both sets of fibers at a negative pressure for optimal gas transfer with the blood.

A pair of inflatable balloons 236 and 238 are disposed interiorly of the two sets of fibers 212 and 214, respectively, with the balloons being made from a tubular stock of polymer wherein the open ends of the tubes are hermetically sealed at one end to the inlet manifold 208 and at the other end to the distal or proximal end outlet manifolds 210 and 206, respectfully. A semi-rigid tube 240 for delivering inflation gas to the balloons passes through the proximal end outlet manifold 206 and is hermetically but slidably sealed thereto by a rubber o-ring 242. The gas delivery tube has openings 244 along its length in communication with the interior of both balloons so that the balloons can be inflated and deflated by the injection and removal of helium gas or the like

The distal end 246 of the gas inflation tube is embedded and sealed in the distal end outlet manifold 210.

There are several advantages with this particular embodiment of the invention with one advantage being that while the oxygenator is of a length that is suitable for insertion into the vena cava, the gas delivery fibers themselves are of approximately half the overall length of the device. As mentioned previously, it has been found that better gas transfer can be obtained through shorter fibers carrying the same volume of gas. Another advantage with the oxygenator of this embodiment is that the oxygenator can be placed within the vena cava 248 in direct alignment with the heart 250 so that the oxygenator extends in opposite directions and actually delivers oxygen gas to the blood flowing from both the superior vena cava 248S and the inferior vena cava 248I into the heart 250. Figs. 2-6 are cross-sectional views taken at different locations along the device as illustrated in Fig. 1 to better illustrate the relative positions of the component parts of the oxygenator.

It will be appreciated from the above description of the present invention that different embodiments of the oxygenator of the present invention have been illustrated which improve the gas transfer capabilities of intravenous fiber membrane oxygenators. Part of the improvement is felt to be due to the fact that the fibers extend at a transverse angle to the longitudinal axis of the oxygenator and also due to the fact that in several embodiments, the fibers have been shortened while retaining a desired surface area contact with the blood. Further, the embodiment of Figs. 1- 6 provides the advantage of delivering oxygen gas in two opposite directions so that the device is ideally suited for placement in direct alignment with the heart to oxygenate blood flowing from two opposite directions.

Although the present invention has been described with a certain degree of particularity, it is understood that the present disclosure has been made by way of example, and changes in detail of structure may be made without departing from the scope of the invention, as defined in the appended claims.

Claims

1. An elongated intravenous percutaneous oxygenator having a longitudinal axis comprising in combination a first and second set of hollow gas permeable and liquid impermeable fibers, the fibers of each set having an input end and an output end, at least three longitudinally spaced manifolds in communication with one of said input ends or output ends of said fibers, gas delivery means in communication with the input ends of said fibers and gas exhaust means in communication with said output ends of said fibers such that gas can be passed through said fibers and the manifolds associated therewith.

2. An elongated intravenous percutaneous oxygenator having a longitudinal axis comprising in combination, a first and a second set of hollow gas permeable and liquid impermeable fibers, the fibers of each set having an input end and an output end, at least three longitudinally spaced manifolds in communication with one of said input ends or output ends of said fibers, gas delivery means in communication with the input ends of said fibers and gas exhaust means in communication with said output ends of said fibers such that gas can be passed through each set of said fibers and the manifolds associated therewith, inflatable balloon means disposed longitudinally of said oxygenator so as to be surrounded by said fibers, and gas inflation means in communication with said balloon means for inflating and deflating the balloon means.

3. The oxygenator of claim 2 wherein said manifolds are aligned along the longitudinal axis of the oxygenator and there are three of said manifolds, the middle one of said manifolds being in communication with one of said input or output ends of said fibers and the other two manifolds being in communication with the other of said input ends or out ends of said fibers.

4. The oxygenator of claim 3 wherein said balloon means extends between said middle one of said manifolds and the other two of said manifolds.

5. The oxygenator of claim 4 wherein one of said gas delivery and gas exhaust means are in communication with the middle one of said manifolds and the other of said gas delivery or gas exhaust means is in communication with the other two of said manifolds.

6. The oxygenator of claim 5 wherein said balloon means includes two balloons with one balloon extending between said middle manifold and one of said other two manifolds and the other balloon extending between said middle manifold and the other of said other two manifolds and wherein said gas inflation means is in communication with each of said balloons.

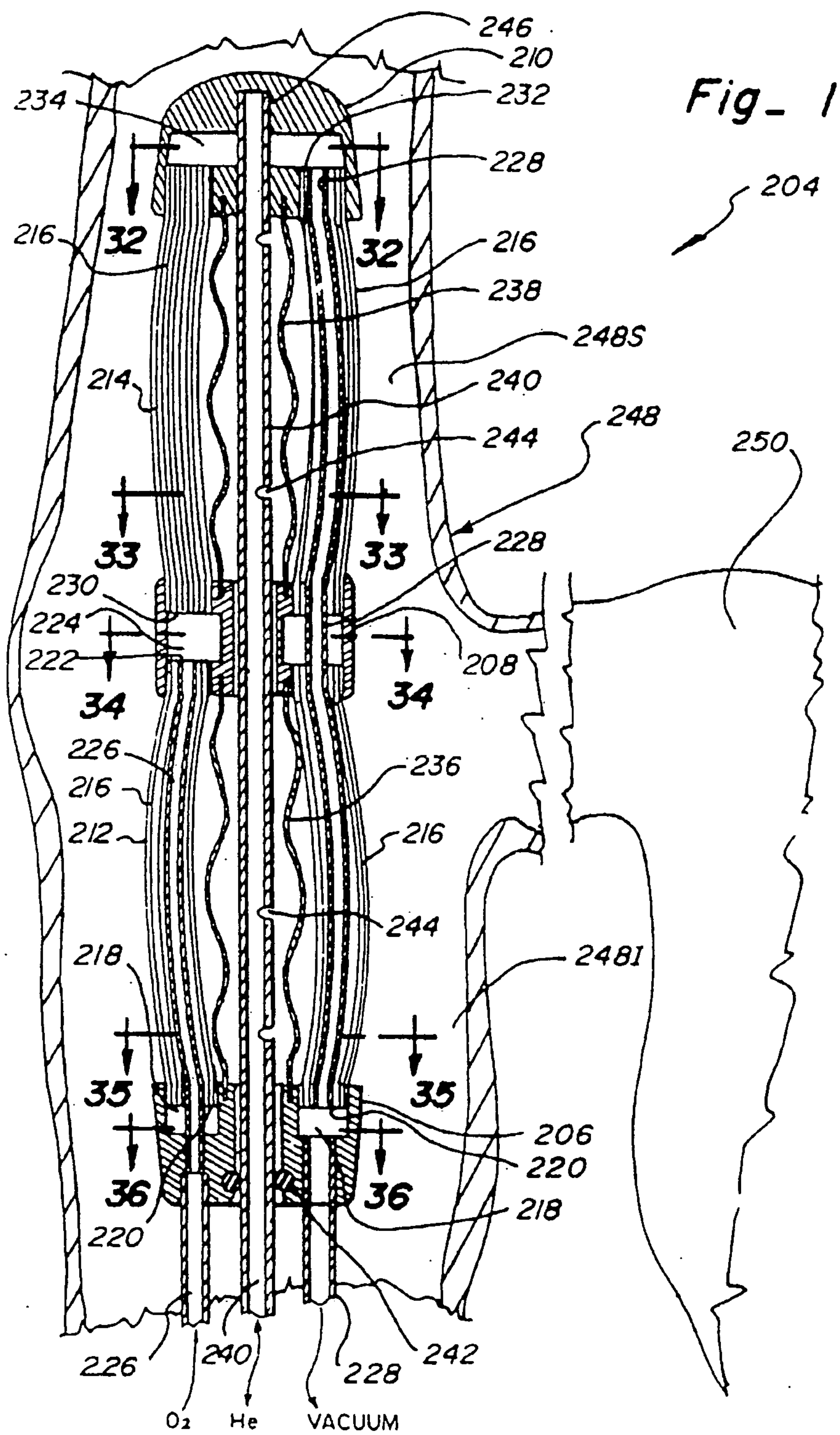
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Fig_ 1

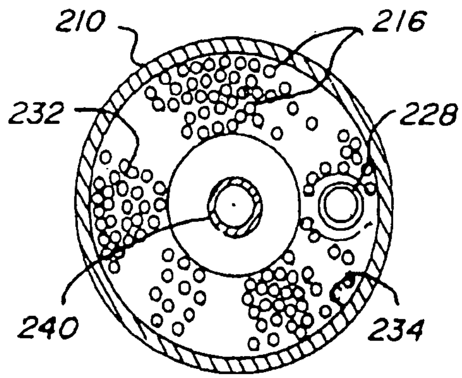

Fig_ 2

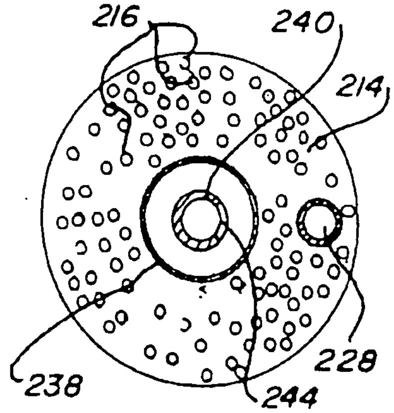

Fig_ 3

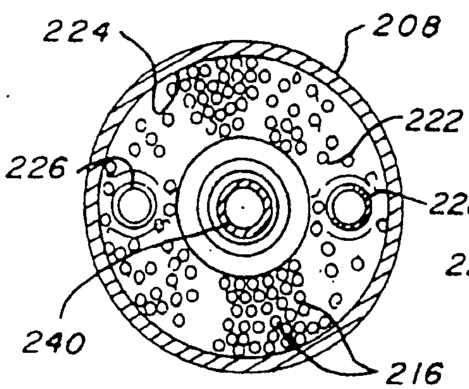

Fig_ 4

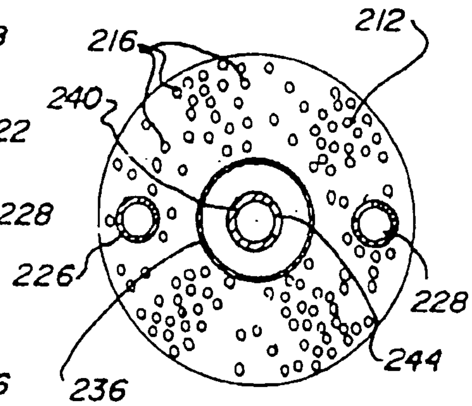

Fig_ 5

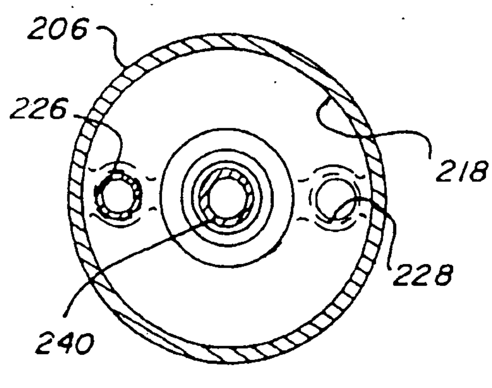

Fig_ 6